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IN THE

Supreme Court of the United States

October Term, 1984

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

v.

ROCHE PRODUCTS, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ROBERT V. MARROW
SALON, MARROW, DYCKMAN & TRAGER
Attorneys for Petitioner
Bolar Pharmaceutical Co., Inc.
41 East 42nd Street
New York, New York 10017
(212) 661-7100

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Questions Presented

1. Is experimental use of a patented invention, which does not affect the patent holders' exclusive exploitation of the invention during the patent term, prohibited by the patent law because the experimentor intends to use the results of the experiment for a business purpose after patent expiration?

2. Can a patent holder extend its monopoly over a prescription drug for two years or more after the patent expires by prohibiting others from using the drug in experiments conducted to satisfy Food and Drug Administration pre-marketing requirements?

Parties to the Proceeding Below

The parties named in the caption are the only parties to this action.

Pursuant to Supreme Court Rule 28.1, petitioner Bolar Pharmaceutical Co., Inc. identifies its parent companies, subsidiaries and affiliates as follows:

Bolar, Inc.
Superior Label Corp.

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Petitioner hereby requests that this Court issue a writ of certiorari to review a judgment of the United States Court of Appeals for the Federal Circuit entered April 23, 1984.

Opinions Below

The opinion of the United States Court of Appeals for the Federal Circuit, which is reported at 733 F.2d 858 (Fed. Cir. 1984), is reprinted as Appendix A, *infra* pp. 1a-

18a of this petition. The opinion of the District Court, reported at 472 F.Supp. 255 (E.D.N.Y. 1983), is reprinted as Appendix B, *infra* pp. 31a-37a.*

Jurisdiction

Review of the Court of Appeals judgment reversing the district court and remanding this case to that court is within this Court's jurisdiction under 28 U.S.C. Section 1254(1). The Court below had jurisdiction premised on 28 U.S.C. Section 1338(a).

Constitutional Provisions and Statutes Cited

United States Constitution Article I, Section 8, Clause 8

Title 21 United States Code Section 355(a)(b)

Title 35 United States Code Section 154

Title 35 United States Code Section 271(a)

Title 35 United States Code Section 283

The pertinent text of these provisions is set forth in Appendix D, *infra* at pp. 40a, 41a.

Statement of the Case

Flurazepam hydrochloride (flurazepam hcl) is the active chemical ingredient in a successful sleeping pill, prescribed for insomnia and sold in the United States exclusively by Roche Products, Inc. (Roche) under the trade name Dalmane. Roche patented flurazepam hcl on January 15, 1967, and, therefore, its patent expired after seventeen years, on January 15, 1984. 35 U.S.C. 154.

* Pages in the Appendix will be referred to by the page number followed by the letter "a".

Bolar Pharmaceutical Co., Inc. (Bolar), a generic drug manufacturer, wanted to begin making and selling generic flurazepam hcl tablets in competition with Roche, as soon as possible after Roche's patent expired.

The development of a generic equivalent to a brand name drug product requires a substantial amount of research and development, testing and experimentation by the generic manufacturer. A generic drug is not simply a copy of the originator. This Court has recently held that a generic drug is a "new drug" and that the Food and Drug Administration (FDA) must approve a New Drug Application (NDA) before a generic drug can be sold, despite the fact that its active ingredients are identical to the originator's. *U.S.* v. *Generix,* —— U.S. ——, 103 S.Ct. 1610, 75 L.Ed.2d 198 (1983). The FDA must be satisfied that the new generic drug is safe and effective (21 U.S.C. 355), i.e., that it delivers the active ingredient to the site of drug action in proper potency and at the proper time. (34a)

A generic drug is a "new drug" despite the fact that its active ingredient is identical to the brand name drug because the inactive ingredients are almost always different. Inactive ingredients, such as fillers, lubricants, binders, releasing agents and sustained release agents, can affect the way that the active ingredient works in the body. Inactive ingredients are trade secrets—Bolar does not know what inactive ingredients are in Roche's Dalmane. The task of Bolar's research and development is to discover a combination of inactive ingredients that, when mixed with the active ingredient, will meet all the FDA's requirements of safety and effectiveness and will work in the body in the same way as Roche's product.

The process of developing a generic product and obtaining FDA approval takes about two years. Bolar must perform dissolution studies, stability studies, bioavailability and bioequivalency studies, and must develop methods to establish that the data produced by these studies accurately support the conclusion that its flurazepam hcl is safe and effective, and will work in the human body much the same as Dalmane.

Because this process of developing and testing generic products in order to obtain FDA approval takes approximately two years, it has been the practice and custom in the pharmaceutical industry for generic companies to begin testing their products and applying for FDA approval well in advance of patent expiration, so that they can have the approval and be ready to enter the market and compete with the brand name product as soon as possible after the patent on the brand name product expires.

In early 1983, following this custom and practice, Bolar purchased five (5) kilograms of flurazepam hcl from a source other than Roche and began testing the product. To the surprise of Bolar and the rest of the generic drug industry, Roche sued Bolar to prohibit Bolar's use of the product in tests and experiments conducted solely for FDA approval.* Five (5) kilograms is not a commercially viable quantity to manufacture a product for sale. Roche knew that Bolar's use of the product was intended only to permit

* Roche brought the action in the U.S. District Court, District of New Jersey. There Judge Sarokin granted a temporary restraining order on the same day Roche moved for that relief, noting that his order did not preclude a different decision by the judge assigned to the case after full consideration. (21a) The case was transferred to the Eastern District of New York on Bolar's motion for a change of venue (28a), and assigned to Judge Wexler.

Bolar to enter the market after patent expiration, and that the effect of Roche's suit, if successful, would be to delay the start of experimentation for FDA approval until after patent expiration, thereby giving Roche and other research oriented pharmaceutical companies an additional period of indefinite duration after patent expiration during which Roche and others like it would have exclusive access to the American market for their drugs. (34a)

Bolar defended the action on the grounds that the Constitution (art. I, section 8, cl. 8) and the Patent Statute (35 U.S.C. 154) state that patent protection can be granted only for "limited times", specifically seventeen years, and that Roche was seeking *de facto* extension of its patent monopoly for an indefinite period in excess of seventeen years, possibly nineteen years or more. Furthermore, Roche's attempt to extend its monopoly into the post-expiration period was based upon requirements imposed on Bolar by the Food, Drug & Cosmetic Act, which is designed to insure safe and effective pharmaceutical products, and not to give a developer of a pioneer product a monopoly of indefinite duration.

Roche claimed Bolar's use of the product was prohibited by the section of the patent law which gives the patent holder the right to exclude others from "making, *using* or selling" the patented invention for the life of the patent. 35 U.S.C. 154 (emphasis added). Bolar countered that the use prohibited by the patent law did not extend to the kind of experimentation engaged in by Bolar, which had no effect on the legitimate rights of the patent holder during the seventeen year life of the patent.

The District Court dismissed Roche's complaint, finding that Bolar's experiments would not be a prohibited use of Roche's patented product, and that their effect on Roche's patent rights were *de minimis.* (36a)

The Court of Appeals for the Federal Circuit rejected Bolar's contentions and reversed the District Court, using language that prohibits not only Bolar's experimental use of flurazepam hcl, but also endangers scientific experimentation with any patented product if the ultimate purpose of the experiments is business related:

> "Bolar's intended 'experimental' use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. Bolar's intended use of flurazepam hcl to derive FDA required test data is thus an infringement of the '053 patent. Bolar may intend to perform 'experiments,' but unlicensed experiments conducted with a view to the adaption of the patented invention to the experimentor's business is a violation of the rights of the patentee to exclude others from using his patented invention." (9a)

The Court of Appeals remanded the case to the District Court solely for the imposition of a remedy.

The Court of Appeals decision extends for years after patent expiration the monopolies of patent holders in the pharmaceutical industry by misinterpreting the section of the patent law which prohibits unlicensed use of a patented product. That prohibition has traditionally been applied to uses which interfere with the interest of the patent holder in exploiting his invention, and not to innocuous uses, such as experimental use, which do not affect the right of the

patent holder to exploit his invention. For decades such experimental use has gone unchallenged by Roche and all other large pharmaceutical companies, despite their knowledge of its existence based on hundred of FDA approvals issued before, or just after patent expiration.

What follows is an analysis of the errors made by the Court of Appeals in finding Bolar's use to be patent infringement, and a discussion of the compelling reasons to review the Court of Appeals decision based on its effect on the pharmaceutical industry, scientific research, government purchases of drug products and the cost of medicine to that segment of the public least able to afford an extension of drug monopolies, the ill and the elderly.

Reasons for Granting the Writ

I

The Decision Below Extends Drug Patent Monopolies for Indefinite Periods Beyond Patent Expiration, and Conflicts With the Constitution, the Patent Law and Decisions of This Court.

The Constitution authorizes Congress to secure "for limited times" to inventors "the exclusive right" to their inventions and discoveries. U.S. Const., art. I, sec. 8, cl. 8.

Because a patent is an exception to both the general prohibition against monopolies and the valued right of access to a free and open market, *Walker Process Equipment Inc.* v. *Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), it is by its very nature affected with a public interest. *Seymour* v. *Osborne*, 78 U.S. 516, 533 (1870). The law is

carefully designed to accommodate the tension between two conflicting public policies—one to encourage invention and the other to foster competition by making the invention available to the public. Invention is encouraged by granting a patent monopoly, competition is fostered by requiring disclosure of the patented invention and limiting the patent monopoly. The Congress has determined seventeen years to be the appropriate monopoly period to encourage invention. 35 U.S.C. 154.

By interpreting the patent statute to prohibit experimental use of patented chemical entities by drug companies which must have FDA approval to sell their competing products, the decision of the court below adds an indefinite period to the 17 year patent grant.

This decision conflicts with the Constitution because it gives the patentee a monopoly of indefinite duration where the Constitution mandated that the exclusive rights granted by the patent be "for limited times." It also conflicts with the statute itself, which limits patent duration to 17 years.

Furthermore, the decision conflicts with this Court's consistent view that:

> ". . . any attempted reservation or continuation in the patentee or those claiming under him of the patent monopoly, after the patent expires, whatever the legal device employed, runs counter to the policy and purpose of the patent laws."
>
> *Scott Paper Co.* v. *Marcalus Co.*, 326 U.S. 249, 256, 90 L.Ed. 47, 51, 66 S.Ct. 101

See also Singer Mfg. Co. v. *June Mfg. Co.*, 163 U.S. 169, 185, 41 L.Ed. 118, 124, 16 S.Ct. 1002 (1895); *Kellogg Co.* v.

National Biscuit Co., 305 U.S. 111, 118, 83 L.Ed. 73, 78, 59 S.Ct. 109 (1938); *Brulotte* v. *Thys Co.*, 379 U.S. 29, 31, 13 L.Ed.2d 99, 101, 85 S.Ct. 176.

In the case at bar, the public interest in a free and open market after patent expiration is particularly acute because of the nature of the product involved, a prescription drug. Competition between generic drug manufacturers and name-brand drug companies significantly reduces the cost of medication for those most in need, usually the sick and the elderly. *Virginia State Board of Pharmacy* v. *Virginia Citizens' Consumer Counsel*, 425 U.S. 748, 763 (1976).

It is not the purpose of the Food, Drug & Cosmetic Act, or the FDA regulations promulgated thereunder, to extend pioneer drug manufacturers' exclusive dominion over the American market.

> "The Federal Food, Drug and Cosmetic Act and the underlying regulations governing the approval for the marketing of new drugs were not intended to provide patent-like protection for a seller who has gained approval of a pioneer drug application."
>
> *Upjohn Mfg. Co.* v. *Schweiker*, 681 F.2d 480 (6th Cir. 1982)

The Court of Appeals noted the enormous importance of the issue presented:

> "At stake in this case is the length of time a pharmaceutical company which has a patent on the active ingredient in a drug can have exclusive access to the American market for that drug." (1a, 2a).

In effect, the Court of Appeals has extended Roche's "exclusive access to the American market" for an indefinite

period *after* patent expiration. The legitimate competition, envisaged by the framers of the Constitution, who required that patents be of *limited* duration (U.S. Const., art. I, sec. 8, cl. 8), and by the legislature, which fixed 17 years as the appropriate length of a patent monopoly (35 U.S.C. 154), will be indefinitely delayed for substantial periods of time if experimenation with drug products requiring FDA premarket approval is prohibited until patent expiration.* A holding that Bolar's FDA related experimentation with flurazepam hcl would be patent infringement extends Roche's monopoly and therefore frustrates an essential purpose of the patent laws, to make inventions available to the public when patents expire.

The decision below conflicts with applicable provisions of the Constitution, the patent statute and with every applicable decision of this Court. It should be reviewed.

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* It is also significant that the Court of Appeals decision and the American patent laws do not apply to Canadian and other foreign manufacturers of generic drugs. These generic firms will be able to do the necessary experimentation and submit applications for premarketing approval to the FDA during the patent term, while American generic drug companies must wait until after patent expiration to begin experimentation. This obviously gives foreign generic drug companies a tremendous advantage over domestic companies (an entry into the United States market approximately two years prior to American companies), a result which could not have been intended by the framers of the Constitution or the patent statute. Another unintended consequence of the Court of Appeals decision will be the shifting of research and development of American generic drug manufacturers from their own laboratories to foreign research facilities.

II

The Court of Appeals Failed to Recognize That the Patent Law Does Not Prohibit Unlicensed Uses Which Do Not Affect the Patent Holder's Rights.

The patent law states that a patent holder can, "exclude others from making, using or selling the invention . . ." 35 U.S.C. 154. Although this broad prohibition literally applies to all making, using or selling of the patented invention, Judge Learned Hand's observation on statutory construction (noted in the opinion below) is particularly applicable here:

> "[I]t is true that the words used, even in their literal sense, are the primary, and ordinarily the most reliable, source of interpreting the meaning of any writing: be it a statute, a contract, or anything else. But it is one of the surest indexes of a mature and developed jurisprudence not to make a fortress out of the dictionary; but to remember that statutes always have some purpose or object to accomplish, whose sympathetic and imaginative discovery is the surest guide to their meaning."
>
> *Cabell* v. *Markam*, 148 F.2d 737, 739 (2d Cir.), *aff'd*, 326 U.S. 464 (1945)

The "surest guide" to the meaning of the use prohibition is the purpose and object of the patent law.

For more than a century courts have considered the underlying purpose and object of patent grants in determining which uses interfere with that purpose and are therefore infringements, as well as which uses do not dis-

turb the interests of the patentee, and therefore are non-infringing.

The patent law has a dual purpose, to encourage invention and to provide public disclosure of inventions. *Mercoid Corporation* v. *Mid-Continent Investment Co.*, 320 U.S. 661, 665, 64 S.Ct. 268 at 271, 88 L.Ed. 376 (1943); *Scott Paper Co.* v. *Marcalus Mfg. Co.*, 326 U.S. 249, 255, 90 L.Ed. 47, 51 (1945). The means employed to accomplish this purpose is the grant of, "a right to be free from competition in the practice of the invention," for a limited time. *Mercoid, supra*, 320 U.S. at 665.

It has long been recognized that it is not necessary or desirable to prohibit all uses of a patented invention in order to secure to the patent holder the exclusive right to exploit his creation. A use which does not disturb the patentee's rights to be free from competition in the practice of his invention does not infringe the patent. Permitted uses of the patented invention have been characterized as experimental, *de minimis*, non-infringing, outside the scope of the patent or in the public interest. *Kaz Manufacturing Co., Inc.* v. *Chesebrough-Pond's, Inc.*, 211 F.Supp. 815 (S.D. N.Y. 1962), *aff'd*, 317 F.2d 679 (2d Cir. 1963); *Celotex Corporation* v. *V.E. Power Door Corp.*, 204 U.S.P.Q. 636 (E.D.N.Y. 1979); *Levin* v. *Ripple Twist Mills*, 416 F.Supp. 876, 881 n. 9 (E.D.Pa. 1976), *appeal dismissed without opinion*, 549 F.2d 795 (3d Cir. 1977); *Arko Argate Company* v. *Master Marble Company*, 18 F.Supp. 305 (N.D.W.Va. 1937); *Maxon Premix Burner Company, Inc.* v. *Eclipse Fuel Engineering Co.*, 471 F.2d 308 (7th Cir. 1972).

Clearly the patent law does not prohibit all unlicensed uses of an invention, and the basis for permitting a par-

ticular unlicensed use is that such use does not interfere with or disturb the legitimate right of the patentee to be free from competition in practicing his invention during the patent term. Bolar's use of flurazepam hcl is in this category. (See Point III)

III

FDA Related Experiments Do Not Interfere With Roche's Rights.

Bolar's use of flurazepam hcl does not threaten or disturb Roche's exclusive right to practice its invention, i.e., to make, use and sell the drug for therapeutic purposes during the life of the patent. Every tablet which was made, used or sold as a sleeping pill in the United States during the life of the patent was Roche's. FDA related experimentation does not disturb in the slightest Roche's exclusive access to the American market, which provides the incentive to invent at the heart of the patent law.

Roche's patent, "insures against another doing substantially the same thing in substantially the same way as the patentee." 69 C.J.S. Patents, p. 72, quoted in *Kaz Manufacturing Co.* v. *Chesebrough-Pond's, Inc., supra.* FDA related experiments do not infringe the patent because they do not use the patented drug in the same way as the patentee uses the drug.

Professor Robinson defines the interest of the patentee as follows: "The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others." (W. Robin-

son, *The Law of Patents for Useful Inventions*, Section 898 (1890)). This Court has defined the patentee's interest as, "a right to be free from competition in the practice of the invention." *Mercoid Corp.* v. *Mid-Continent Investment Co., supra,* 320 U.S. at 665. Inherent in the very term "practice the invention" (a term of art frequently used by courts, attorneys and scholars in connection with patents) is a type of use which exploits the invention. Experimenting with the product is not "practicing the invention". Roche made, used and sold the drug for therapeutic purposes, Bolar did not. Bolar did not practice the invention; rather it wanted to use the product in experiments to develop data for its FDA application, a use that has no effect on Roche during the life of the patent. Whether characterized as experimental, *de minimis*, or otherwise, Bolar's experiments were non-infringing use.

The Court of Appeals found FDA related experiments infringing because they are conducted, "for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." (9a) Clearly, the court below focused on Bolar's motives instead of the effect on Roche's patent rights. This emphasis on the motive of the accused infringer leads to error because the objectives of the patent law are directed to encouraging innovation by benefiting the patentee. Focusing on the motive of the alleged infringer, the court misses the salient point; Bolar's experimental use does not disturb the benefits granted to Roche during the patent term, and therefore Bolar's use does not diminish the incentive to invent.

By performing experiments for its FDA application before Roche's patent expired, Bolar may gain the advan-

tage of entering the market earlier after patent expiration than it otherwise would if it had to wait for patent expiration to begin its experiments. Roche points to this advantage sought by Bolar, which can be substantial, and argues that the use, and Roche's injury, are not *de minimis*. In making this argument, Roche fails to recognize an essential distinction between the period before patent expiration and the period after its patent expires. Roche's only injury occurs as the result of competition after the patent expires, and Roche has no right to be free from competition in that period. As the Supreme Court stated in *Scott Paper Co.* v. *Marcalus Co.*, 326 U.S. 249, 256 (1965):

> ". . . any attempted reservation or continuation in the patentee or those claiming under him of the patent monopoly, after the patent expires, whatever the legal device employed, runs counter to the policy and purpose of the patent laws."

See also Brulotte v. *Thys Co.*, 379 U.S. 29 (1964).

FDA related experiments, which take place during the patent period, are non-infringing because they do not disturb Roche's right to fully exploit the invention. The fact that those pre-patent expiration experiments permit Bolar to enter the marketplace and compete with Roche at an earlier date cannot form the basis of any claim of patent infringement because competition takes place exclusively after the patent expires.

Roche also argued below that Bolar's FDA related use would infringe Roche's right to license that use, and was therefore commercially detrimental to Roche's patent rights. This contention ignores the reality that Roche never has and never would license such use. Moreover, it is

repugnant to the very purposes of the FDA premarketing regulations to permit Roche to profit from FDA regulations which were intended only to assure safe and effective drugs for the public, rather than to swell brand name drug companies' profits. *See Upjohn Mfg. Co. v. Schweiker*, 681 F.2d 480 (6th Cir. 1982).

As Judge Wexler found after trial, FDA related experiments before patent expiration are non-infringing because they do not disturb or impinge upon Roche's rights to be free of competition in the practice of its invention during the 17 years covered by the patent grant. (37a)

IV

The Experimental Use Doctrine Should Be Defined by This Court to Permit Scientific Experimentation Which Does Not Interfere With the Patent Grant Although the Ultimate Motive of the Experimentor Is to Use the Results of His Experiments for Business Purposes After Patent Expiration.

It is essential that the "experimental use" doctrine be reviewed by this Court. Experimental use as defined by the Court of Appeals (i.e., experimentation solely for amusement, so satisfy idle curiosity or for strictly philosophical purposes [9a]) is meaningless, because virtually all serious research and experimentation has some ultimate business purpose. The very purpose of the patent law, to encourage research, experimentation and invention, is turned on its head by this decision which can effectively curtail much useful scientific creativity.

In the pharmaceutical industry the Court of Appeals decision delays for years research and development to create "new drugs"—generic equivalents of expensive brand name products—despite the fact that such research and development has no effect on the patent holder's exclusive right to practice his invention and profit from that practice during the patent term.

Prior to this decision, experimental projects by generic drug companies to develop inexpensive equivalents to brand name drug products were accepted by the pharmaceutical community as a lawful and permissible use of patented products. The FDA has approved pre-marketing applications for generic companies on numerous drug products *prior to patent expiration.* Those applications obviously were based on data obtained from experimental use of the patented products prior to patent expiration. At this very moment most, if not all, generic drug manufacturers have pending with the FDA pre-marketing applications for patented drugs based on data obtained from experiments using the patented product. The decision can create chaos in the generic drug industry if the experimentation upon which hundreds of FDA approvals have previously been granted suddenly becomes illegal.

The magnitude of this problem is immense because the Court of Appeals decision requires federal courts to grant substantial damages or injunctions in all cases where experimentation has produced data now contained in pending FDA applications. For example, Roche has already commenced demanding from all generic companies that have experimented with diazepam hcl (the active ingredient in Valium, the patent for which expires in 1985) information

concerning their FDA related use of that drug ingredient. The Court of Appeals decision creates chaos where there had previously been a common understanding in the industry that experimentation with such drugs was a protected use leading to competition after patent expiration. The enormity of the chaos is truly staggering when the flurazepam hcl and diazepam hcl situations are multiplied by the number of drugs in which generic companies correctly assumed their experimentation was lawful.

It never even occurred to patent holders to question the right of generic companies to use patented products in FDA mandated experiments, until the aberrant case of *Pfizer, Inc.* v. *International Rectifier Corp.*, 217 U.S.P.Q. 157 (C.D. Cal. 1982) was reported. That case was based upon an unusual "defiance of court decrees" (15a) by the defendant, and arose in a context far different from that in the case at bar or the common situation where generic companies have experimented with patented products as part of the ordinary course of business accepted as proper for decades by all segments of the pharmaceutical industry. The Court of Appeals decision has taken the limitation on experimental use imposed upon a defiant infringer in *Pfizer*, and imposed it upon the entire generic drug industry.

Moreover, the broad language adopted by the Court of Appeals extends the limitation on the experimental use doctrine to the scientific community in general, where research using patented products has always been accepted as lawful. That belief is suddenly brought into question by the Court of Appeals decision. (*See Science* Vol. 224, 8 June 1984, p. 1080, published by the American Association of the Advancement of Science, Appendix E.)

These limitations on experimental use of patented products are based solely on the acknowledged fact that the results of the experiments will have a business related use after patent expiration. (9a) However, it is not the intent of the experimentor, be he dilettante or businessman, that he should control the application of the experimental use doctrine; rather, the effect of the experiments on the patent holder should be the criterion. Even Professor Robinson, whose language the Court of Appeals adopts to define the experimental use doctrine, recognized that there is, "No Act of Infringement Unless it Affects the Pecuniary Interests of the Owner of the Patented Invention."

> "[T]he interest to be promoted by the wrongful employment of the invention must be hostile to the interest of the patentee. The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others."
>
> (W. Robinson, *The Law of Patents and Useful Inventions*, Section 998 (1890), quoted by the C.A.F.C. at 7a)

Only by judging experimental use by that standard (i.e., does it diminish the emoluments which the patentee does or might receive?), and not by the intent of the experimentor, can a court determine whether the act of the experimentor diminishes the patent grant by interfering with or disturbing the commercial monopoly which provides the incentive to invent at the core of the patent law.

It has traditionally been for the courts, not the legislature, to define experimental use. It is disingenuous for the Court of Appeals to say that the patent statute is clear on its face, and it is up to the Congress, not the courts, to

analyze the experimental use doctrine as it applies to this case. If that were true, there would be no experimental use doctrine and any use would be actionable, regardless of the experimentor's intent or the *de minimis* effect on the patent grant.

Unless reversed, this decision will inhibit the advancement of scientific knowledge and the development of useful drugs and inventions which the patent law was intended to foster and encourage.

Conclusion

This case does not involve technical questions of patent validity as to which the court might defer to the scientific expertise of the members of the C.A.F.C. Rather, general questions of policy and jurisprudence are presented by this case.

A federal court of appeals has decided an important question of federal law which has not been, but should be settled by this Court. The decision below conflicts with applicable decisions of this Court by extending Roche's patent monopoly for an indefinite period beyond the patent term.

It is respectfully requested that a Writ of Certiorari issue to review the judgment of the United States Court of Appeals for the Federal Circuit.

Respectfully submitted,

Robert V. Marrow
Salon, Marrow, Dyckman & Trager
Attorneys for Petitioner
Bolar Pharmaceutical Co., Inc.

APPENDICES

APPENDIX A

Decision of United States Court of Appeals for the Federal Circuit

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Appeal No. 84-560

ROCHE PRODUCTS, INC.,
Appellant,

v.

BOLAR PHARMACEUTICAL CO., INC.,
Appellee.

DECIDED: April 23, 1984

Before MARKEY, *Chief Judge,* NICHOLS, *Senior Circuit Judge,* and KASHIWA, *Circuit Judge.*

NICHOLS, *Senior Circuit Judge.*

This is an appeal from a judgment entered on October 14, 1983, in which the United States District Court for the Eastern District of New York held United States Patent No. 3,299,053 not infringed and denied relief. We *reverse* and *remand.*

I

At stake in this case is the length of time a pharmaceutical company which has a patent on the active ingredient in a drug can have exclusive access to the American market

for that drug. Plaintiff-appellant Roche Products, Inc. (Roche), a large research-oriented pharmaceutical company, wanted the United States district court to enjoin Bolar Pharmaceutical Co., Inc. (Bolar), a manufacturer of generic drugs, from taking, during the life of a patent, the statutory and regulatory steps necessary to market, after the patent expired, a drug equivalent to a patented brand name drug. Roche argued that the *use* of a patented drug for federally mandated premarketing tests is a *use* in violation of the patent laws.

Roche was the assignee of the rights in U.S. Patent No. 3,299,053 (the '053 patent), which expired on January 17, 1984. The '053 patent, which issued on January 17, 1967, is entitled "Novel 1 and/or 4-substituted alkyl 5-aromatic-3H-1,4-benzodiazepines and benzodiazepine-2-ones." One of the chemical compounds claimed in the '053 patent is flurazepam hydrochloride (flurazepam hcl), the active ingredient in Roche's successful brand name prescription sleeping pill "Dalmane."

In early 1983, Bolar became interested in marketing, after the '053 patent expired, a generic drug equivalent to Dalmane. Because a generic drug's commercial success is related to how quickly it is brought on the market after a patent expires, and because approval for an equivalent of an established drug can take more than 2 years, Bolar, not waiting for the '053 patent to expire, immediately began its effort to obtain federal approval to market its generic version of Dalmane. In mid-1983, Bolar obtained from a foreign manufacturer 5 kilograms of flurazepam hcl to form into "dosage form capsules, to obtain stability data, dissolution rates, bioequivalency studies, and blood serum studies" necessary for a New Drug Application to the United States Food and Drug Administration (FDA).

On July 28, 1983, Roche filed a complaint in the United States District Court for the District of New Jersey against three parties: Bolar, Bolar's principal officer, and the importer of the infringing flurazepam hcl. Only Bolar remains a party defendant. Roche sought to enjoin Bolar from using flurazepam hcl for any purpose whatsoever during the life of the '053 patent. When Bolar stated during discovery, on August 30, 1983, that it intended immediately to begin testing its generic drug for FDA approval, Roche moved for and was granted a Temporary Restraining Order, on September 2, 1983.

On September 26, 1983, Bolar was granted a change of venue and the case was transferred to the United States District Court for the Eastern District of New York. That court consolidated Roche's motion for a preliminary injunction with the trial on the merits pursuant to Fed. R. Civ. P. 65(a)(2) (both parties had stipulated to all the pertinent facts so no testimony was necessary) and on October 11, 1983, issued a Memorandum and Order denying Roche's application for a permanent injunction. The court held that Bolar's use of the patented compound for federally mandated testing was not infringement of the patent in suit because Bolar's use was *de minimis* and experimental. The court entered judgment for Bolar on October 14, 1983, and Roche filed its notice of appeal that same day.

II

The district court correctly recognized that the issue in this case is narrow: does the limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements during the last 6 months of the term of the patent constitute a use which, unless licensed, the

patent statute makes actionable? The district court held that it does not. This was an error of law.

III

A

When Congress enacted the current revision of the Patent Laws of the United States, the Patent Act of 1952, ch. 950, 66 Stat. 792 (codified at 35 U.S.C.), a statutory definition of patent infringement existed for the first time since section 5 of the Patent Act of 1793 was repealed in 1836. Title 35 U.S.C. § 271(a) incorporates the disjunctive language of the statutory patent grant which gives a patentee the "right to exclude others from making, using, or selling" a patented invention, 35 U.S.C. § 154. Congress states in section 271(a):

> [W]hoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent.

It is beyond argument that performance of only *one* of the three enumerated activities is patent infringement. It is well-established, in particular, that the *use* of a patented invention, without either manufacture or sale, is actionable. *See Aro Manufacturing Co.* v. *Convertible Top Replacement Co.*, 377 U.S. 476, 484, 141 USPQ 681, 685 (1964); *Coakwell* v. *United States*, 372 F.2d 508, 510, 153 USPQ 307, 308 (Ct. Cl. 1967). Thus, the patentee does not need to have *any* evidence of damage or lost sales to bring an infringement action.

Section 271(a) prohibits, on its face, any and all uses of a patented invention. Of course, as Judge Learned Hand

observed in *Cabell* v. *Markham*, 148 F.2d 737, 739 (2d Cir.), *aff'd*, 326 U.S. 464 (1945):

> [I]t is true that the words used, even in their literal sense, are the primary, and ordinarily the most reliable, source of interpreting the meaning of any writing: be it a statute, a contract, or anything else. But it is one of the surest indexes of a mature and developed jurisprudence not to ake a fortress out of the dictionary; but to remember that statutes always have some purpose or object to accomplish, whose sympathetic and imaginative discovery is the surest guide to their meaning.

Because Congress has never defined use, its meaning has become a matter of judicial interpretation. Although few cases discuss the question of whether a particular use constitutes an infringing use of a patented invention, they nevertheless convincingly lead to the conclusion that the word "use" in section 271(a) has never been taken to its utmost possible scope. *See, e.g., Pitcairn* v. *United States*, 547 F.2d 1106, 192 USPQ 612 (Ct. Cl. 1976), *cert. denied*, 434 U.S. 1051 (1978) (experimental use may be a defense to infringement); *United States* v. *Univis Lens Co.*, 316 U.S. 241 (1942) ("An incident to the purchase of any article, whether patented or unpatented, is the right to use and sell it, * * *." *Id.* at 249); *General Electric Co.* v. *United States*, 572 F.2d 745, 198 USPQ 65 (Ct. Cl. 1978) ("[I]t can be properly assumed that as part of the bargain the seller of a device incorporating a patented combination * * * authorizes the buyer to continue to use the device so long as the latter can and does use the elements he purchased from the patentee or licensor." *Id.* at 784-85, 198 USPQ at 98).

Bolar argues that its intended use of flurazepam hcl is excepted from the use prohibition. It claims two grounds for exception: the first ground is based in a liberal interpretation of the traditional experimental use exception; the second ground is that public policy favors generic drugs and thus mandates the creation of a new exception in order to allow FDA required drug testing. We discuss these arguments *seriatim*.

B

The so-called experimental use defense to liability for infringement generally is recognized as originating in an opinion written by Supreme Court Justice Story while on circuit in Massachusetts. In *Whittemore* v. *Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600), Justice Story sought to justify a trial judge's instruction to a jury that an infringer must have an intent to use a patented invention for profit, stating:

> [I]t could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.

Despite skepticism, *see, e.g.*, *Byam* v. *Bullard*, 4 F. Cas. 934 (C.C.D. Mass. 1852) (No. 2,262) (opinion by Justice Curtis), Justice Story's seminal statement evolved until, by 1861, the law was "well-settled that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement is not an infringement of the rights of the patentee." *Peppenhausen* v. *Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279). (For a detailed history and analysis of the

experimental use exception, *see* Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. Pat. Off. Soc'y 357 (1957).) Professor Robinson firmly entrenched the experimental use exception into the patent law when he wrote his famous treatise, W. Robinson, *The Law of Patents for Useful Inventions* § 898 (1890):

> § 898. No Act an Infringement unless it affects the Pecuniary Interests of the Owner of the Patented Invention.
>
> [T]he interest to be promoted by the wrongful employment of the invention must be hostile to the interest of the patentee. The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others. These, though not always taking the shape of money, are of a pecuniary character, and their value is capable of estimation like other property. Hence acts of infringement must attack the right of the patentee to these emoluments, and either turn them aside into other channels or prevent them from accruing in favor of any one. An unauthorized sale of the invention is always such an act. But the manufacture or the use of the invention may be intended only for other purposes, and produce no pecuniary result. *Thus where it is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promotion of the employer's knowledge or the relaxation afforded to his mind.* But if the products of the experiment are sold, or used for the convenience of the experimentor, or if the experiments are conducted with a view to the adaptation of the invention to the experimentor's business, the acts of making or of use are violations of the rights of the inventor and infringe-

> ments of his patent. In reference to such employments of a patented invention the law is diligent to protect the patentee, and even experimental uses will be sometimes enjoined though no injury may have resulted admitting of positive redress. [Emphasis supplied, footnotes omitted.]

The Court of Claims, whose precedents bind us, on several occasions has considered the defense of experimental use. *See Ordnance Engineering Corp.* v. *United States,* 84 Ct. Cl. 1, 32 USPQ 614 (1936), *cert. denied,* 302 U.S. 708, 37 USPQ 842 (1937); *Chesterfield* v. *United States,* 159 F. Supp. 371, 116 USPQ 445 (Ct. Cl. 1958); *Douglas* v. *United States,* 181 USPQ 170 (Ct. Cl. Tr. Div. 1974), *aff'd,* 510 F.2d 364, 184 USPQ 613 (Ct. Cl.), *cert. denied,* 423 U.S. 825 (1975); *Pitcairn* v. *United States,* 547 F.2d 1106, 192 USPQ 612 (Ct. Cl. 1976), *cert. denied,* 434 U.S. 1051 (1978). Bolar concedes, as it must, that its intended use of flurazepam hcl does not fall within the "traditional limits" of the experimental use exception as established in these cases or those of other circuits. Its concession here is fatal. Despite Bolar's argument that its tests are "true scientific inquiries" to which a literal interpretation of the experimental use exception logically should extend, we hold the experimental use exception to be truly narrow, and we will not expand it under the present circumstances. Bolar's argument that the experimental use rule deserves a broad construction is not justified.

Pitcairn, the most persuasive of the Court of Claims cases concerning the experimental use defense, sets forth the law which must control the disposition of this case: "[t]ests, demonstrations, and experiments * * * [which] are in keeping with the legitimate business of the * * *

[alleged infringer]" are infringements for which "[e]xperimental use is not a defense." 547 F.2d at 1125-1126, 192 USPQ at 625. We have carefully reviewed each of the other Court of Claims cases, and although they contain some loose language on which Bolar relies, they are unpersuasive. The *Ordnance Engineering* case provides no guidance concerning the boundaries of an appropriately applied experimental use rule other than flatly stating that a device must have been "built for experimental purposes." In *Chesterfield*, the court's flat declaration that "experimental use does not infringe" is pure *obiter dictum*. *See Pitcairn*, 547 F.2d at 1125, 192 USPQ at 625. *Douglas* has no precedential value here since the Court of Claims never affirmed the part of the trial judge's opinion dealing with experimental use; moreover, Trial Judge Cooper's well-reasoned analysis of the experimental use rule concluded that no case had permitted a pattern of systematic exploitation of a patented invention for the purpose of furthering the legitimate business interests of the infringer. The authority of Trial Judge Cooper's views rests on his reputation as a fine patent lawyer, and on their own intrinsic persuasiveness.

Bolar's intended "experimental" use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. Bolar's intended use of flurazepam hcl to derive FDA required test data is thus an infringement of the '053 patent. Bolar may intend to perform "experiments," but unlicensed experiments conducted with a view to the adaption of the patented invention to the experimentor's business is a violation of the rights of the patentee to exclude others from using his patented invention. It is obvious here that it is a misnomer to call the intended use *de minimis*. It is no trifle in its economic

effect on the parties even if the quantity used is small. It is no dilettante affair such as Justice Story envisioned. We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of "scientific inquiry," when that inquiry has definite, cognizable, and not insubstantial commercial purposes.

C

Bolar argues that even if no *established* doctrine exists with which it can escape liability for patent infringement, public policy requires that we create a new exception to the use prohibition. Parties and *amici* seem to think, in particular, that we must resolve a conflict between the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301-392 (1982), and the Patent Act of 1952, or at least the Acts' respective policies and purposes. We decline the opportunity here, however, the engage in legislative activity properly only for the Congress.

The new drug approval procedure which existed between 1938 and 1962 was relatively innocuous and had little impact on the development of pioneer prescription new drugs. Section 505 of the FDCA, ch. 675, 52 Stat. 1052 (1938), required the manufacturer of a pioneer new drug to submit to the FDA a New Drug Application (NDA) containing information concerning the safety of the drug. If the FDA did not disapprove the new drug within 60 days after it received the NDA, marketing could begin.

The provisions of the Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780, caused a substantial increase in the time required for development and approval of a pioneer new drug. Beginning in 1962, the amended Section 505 (codified at 21 U.S.C. § 355 (1982)) required an NDA to

contain proof of efficacy (effectiveness) as well as safety, and required the FDA affirmatively to approve the NDA rather than just to permit marketing by inaction. A recent study indicated that it now can take on average from 7 to 10 years for a pharmaceutical company to satisfy the current regulatory requirements. National Academy of Engineering, *The Competitive Status of the U. S. Pharmaceutical Industry* 79-80 (1983).

Because most FDA-required testing is done after a patent issues, the remaining effective life of patent protection assertedly may be as low as 7 years. *Id., citing* Statement of William M. Wardell to the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, U. S. House of Representatives, Feb. 14, 1982, at 14. Litigation such as this is one example of how research-oriented pharmaceutical companies have sought to regain some of the earning time lost to regulatory entanglements. They gain for themselves, it is asserted, a *de facto* monopoly of upwards of 2 years by enjoining FDA-required testing of a generic drug until the patent on the drug's active ingredient expires.

Bolar argues that the patent laws are intended to grant to inventors only a limited 17-year property right to their inventions so that the public can enjoy the benefits of competition as soon as possible, consistent with the need to encourage invention. The FDCA, Bolar contends, was only intended to assure safe and effective drugs for the public, and not to extend a pharmaceutical company's monopoly for an indefinite and substantial period of time while the FDA considers whether to grant a pre-marketing clearance. Because the FDCA affected prevailing law, namely the Patent Act, Bolar argues that we should apply the patent laws to drugs differently.

Simply because a later enacted statute affects in some way an earlier enacted statute is poor reason to ask us to rewrite the earlier statute. Repeals by implication are not favored. *See, e.g., Mercantile National Bank* v. *Langdeau,* 371 U.S. 555, 565 (1963). Thus, "courts are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective." *Morton* v. *Mancari,* 417 U.S. 535, 551 (1974). There is no affirmative obligation on Congress to explain why it deems a particular enactment wise or necessary, or to demonstrate that it is aware of the consequences of its action. *See Harrison* v. *PPG Industries, Inc.,* 446 U.S. 578, 592 (1979). Rather, because "laws are presumed to be passed with deliberation, and with full knowledge of all existing ones on the same subject," T. Sedgwick, *The Interpretation and Construction of Statutory and Constitutional Law* 106 (2d ed. 1874), we must presume Congress was aware that the FDCA would affect the earning potentiality of a drug patent, and chose to permit it. Although arguably Title 21 and Title 35 are not laws on the "same subject," we note that during Congress' deliberations on the 1962 amendments to the FDCA, it considered the relationship and interaction of the patent laws with the drug laws. *See* S. Rep. No. 1744, 87th Cong., 2d Sess., *reprinted in* 1962 U.S. Code Cong. & Ad. News 2884, 2911-2915.

It is the role of Congress to maximize public welfare through legislation. Congress is well aware of the economic and societal problems which the parties debate here, and has before it legislation with respect to these issues. *See* H.R. 3605, 98th Cong., 1st Sess. (1983) ("Drug Price Competition Act of 1983") (amending 21 U.S.C. § 355(b) to

allow faster marketing of new generic drugs equivalent to approved new drugs); S. 1306, 98th Cong., 1st Sess. (1983) ("Patent Term Restoration Act of 1983") (amending 35 U.S.C. § 155 to add to the patent grant a period of time equivalent to that lost due to regulatory delay), Cong. Rec. S. 6863 (daily ed. May 17, 1983), 26 Pat. Trademark & Copyright J. (BNA) 87-88 (May 26, 1983). No matter how persuasive the policy arguments are for or against these proposed bills, this court is not the proper forum in which to debate them. Where Congress has the clear power to enact legislation, our role is only to interpret and apply that legislation. "[I]t is not our job to apply laws that have not yet been written." *Sony Corp. of America* v. *Universal City Studios, Inc.*, 52 U.S.L.W. 4090, 4100, 220 USPQ 665, 684 (U.S. Jan. 17, 1984) (No. 81-1687). We will not rewrite the patent laws here.

IV

The district court refused to grant a permanent injunction against Bolar because it believed the law did not require that it find infringement of the '053 patent. Since we hold that there is infringement, Roche is entitled to a remedy. We are not in a position, however, to decide the form of that remedy.

Roche requested us, at first, to remand this case to the district court with instructions to enter a permanent injunction against infringement by Bolar. After the main briefs were filed, but before oral argument, the '053 patent expired. This case is not moot, however, because although the initially requested order no longer is necessary, other remedies can be fashioned to give Roche relief against Bolar's past infringement. Roche requests, for example, an order to

confiscate and destroy the data which Bolar has generated during its infringing activity, *citing, Pfizer, Inc.* v. *International Rectifier Corp.*, 217 USPQ 157 (C.D. Cal. 1982) (granting an injunction of that nature to remedy infringement done in contempt of a court order).

Statute provides the basis for Roche's request for injunctive relief, 35 U.S.C. § 283:

> The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

Section 283, by its terms, clearly makes the issuance of an injunction discretionary: the court *"may grant"* relief *"in accordance with the principles of equity."* The trial court thus has considerable discretion in determining whether the facts of a situation require it to issue an injunction. The scope of relief, therefore, is not for us to decide at the first instance, nor is this the time or place for a discourse on the "principles of equity."

Whether an injunction should issue in *this* case, and of what form it should take, certainly depends on the equities of the case. Bolar, Roche, and *amici* Pharmaceutical Manufacturers Association and Generic Pharmaceutical Industry Association, each detail the "catastrophic" effect our decision for either party will have on the American public health system. It is true that it "is a principle of general application that courts, and especially courts of equity, may appropriately withhold their aid where the plaintiff is using the right asserted contrary to the public interest," *Morton Salt Co.* v. *Suppiger Co.*, 314 U.S. 488, 492 (1941), *reh'g denied*, 315 U.S. 826 (1942). Since "the standards of the

public interest, not the requirements of private litigation, measure the propriety and need for injunctive relief in these cases," *Hecht Co.* v. *Bowles,* 321 U.S. 321, 331 (1944), *rev'g Brown* v. *Hecht Co.,* 137 F.2d 689 (D.C. Cir. 1943), we remand this case to the district court for further proceedings to consider what this interest is and what measures it calls for.

There are other aspects here that might make a tribunal reluctant to select, within the scope of its discretion, relief along the harsher side of the possible scale. The case clearly was regarded by both sides as a test. The good faith with which Bolar acted is undisputed, at least before us. Bolar says it did nothing clandestine, but notified Roche what it was going to do at all times before doing it, so Roche could act promptly to defend what it believed to be its rights. The case may be unlike *Pfizer, Inc., supra,* in that Bolar scrupulously obeyed all court orders while they were in effect, or so it says, whereas in *Pfizer, Inc.,* the infringer acted in defiance of court decrees. The destruction of material in *Pfizer, Inc.,* was ordered after everything milder had proved useless. If other measures can be made sufficient, one might well be reluctant to order destruction of the records of research and tests that may embody information that would contribute to the health and happiness of the human race. All this is, of course, for the district judge to consider so far as he finds the factual predicates established.

The actual infringing acts are said to have all occurred in the relatively brief period between vacation of the lower court's restraining order and the expiration of the patent. Counsel for Roche was candid in explaining that he pushed so hard for the harsh relief he did because he thought any money damages would have to be nominal. The correctness of this belief has not been briefed or argued, and we hesitate

to state a firm position, but tentatively, at least, we are skeptical. It is clear that the economic injury to Roche is, or is threatened to be, substantial, even though the amount of material used in the tests was small. If the patent law precludes substantial damages, there exists a strange gap in the panoply (in its proper meaning, a suit of armor) of protection the patent statutes place around an aggrieved and injured patentee. The district judge, before getting into the issue of equitable relief, must determine if he can deal with the case by adequate money damages. If he can, the predicate for equitable relief of a harsh, or even a mild, character is gone.

Counsel are equally mistaken in their apparent belief that once infringement is established and adjudicated, an injunction must follow. In *Hecht Co.* v. *Bowles, supra,* the statute, unlike the one we have here, was seemingly mandatory by its language that once a violation was shown, an injunction *must* follow, and the D. C. Circuit had so held. But the circumstances made an injunction somewhat repugnant. Hecht Co., an unquestionably legitimate and long-established District of Columbia retailer, had got tangled up in the price control regulations of World War II, and its employees had in good faith unwittingly committed some violations. The situation was ironic in that the Hecht Co. had been a leader in extending the patriotic cooperation of the retail trade in application of the unpopular but necessary retail price controls, and had itself offered its own operation for study as illustrating the problems and how they could be solved.

After discovering some loopholes in the statute, in light of the legislative history, Justice Douglas continued at 329:

> We are dealing here with the requirements of equity practice with a background of several hundred years

> of history. Only the other day we stated that "An appeal to the equity jurisdiction conferred on federal district courts is an appeal to the sound discretion which guides the determinations of courts of equity." *Meredith* v. *Winter Haven,* 320 U.S. 228, 235. The historic injunctive process was designed to deter, not to punish. The essence of equity jurisdiction has been the power of the Chancellor to do equity and to mould each decree to the necessities of the particular case. Flexibility rather than rigidity has distinguished it. The qualities of mercy and practicality have made equity the instrument for nice adjustment and reconciliation between the public interest and private needs as well as between competing private claims. We do not believe that such a major departure from that long tradition as is here proposed should be lightly implied.

While two justices declined to join in the opinion, none expressed themselves in favor of affirming the D. C. Circuit. In short, if Congress wants the federal courts to issue injunctions without regard to historic equity principles, it is going to have to say so in explicit and even shameless language rarely if ever to be expected from a body itself made up very largely of American lawyers, having, probably, as much respect for traditional equity principles as do the courts. If an injunction was not mandatory in *Hecht Co.* v. *Bowles,* the more permissive statutory language here makes it *a fortiori* that an injunction is not mandatory now.

The application of historic equity principles to the case at bar is in the first instance for the district court.

V

Conclusion

The decision of the district court holding the '053 patent not infringed is reversed. The case is remanded with instructions to fashion an appropriate remedy. Each party to bear its own costs.

REVERSED AND REMANDED

Order of United States Court of Appeals for the Federal Circuit

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Appeal No. 84-560.

ON MOTION

ROCHE PRODUCTS, INC.,
Plaintiff-Appellant,

v.

BOLAR PHARMACEUTICAL CO., INC.,
Defendant-Appellee.

Before BALDWIN, *Circuit Judge.*

ORDER

Appellant's Second Motion To Expedite Appeal And To Shorten Briefing Schedule is *denied.*

When this case is ultimately heard and decided, and provided that appellant is successful, appellant can seek relief for the alleged infringement despite the expiration of the patent. Moreover, the appeal should not be expedited because appellant is not suffering any damage pending this appeal.

BY DIRECTION

/s/ GEORGE E. HUTCHINSON

George E. Hutchinson, Clerk

Nov. 4, 1983

Date

Order of United States Court of Appeals for the Federal Circuit

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Appeal No. 84-560.

ON MOTION

ROCHE PRODUCTS, INC.,

Appellant,

v.

BOLAR PHARMACEUTICAL CO., INC.,

Appellee.

Before BALDWIN, *Circuit Judge.*

ORDER

Appellant's Motion to Expedite Appeal and to Shorten Briefing Schedule is *denied.*

BY DIRECTION

/s/ GEORGE E. HUTCHINSON

George E. Hutchinson, Clerk

October 24, 1983

Date

APPENDIX B

Opinion of United States District Court for the District of New Jersey

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Civil No. 83-2809

ROCHE PRODUCTS, INC.,

Plaintiff,

against

SST. CORP., BOLAR PHARMACEUTICAL CO., and ROBERT SCHULMAN, (sic)

Defendants.

Newark, New Jersey
September 2, 1983

BEFORE:

THE HONORABLE H. LEE SAROKIN, U.S.D.J.

APPEARANCES:

CRUMMY, DEL DEO, DOLAN & PURCELL, ESQS.
Attorneys for Plaintiff
BY: RALPH DEL DEO, ESQ.

ROBERT V. MARROW, ESQ.
Attorney for Defendants

WILLIAM SOKOL, C.S.R.
Official Court Reporter

THE COURT: This is an application for an Order to Show Cause and a Temporary Restraining Order.

Based upon the papers which have been submitted and the arguments which took place yesterday, the following facts appear to be undisputed:

The plaintiff, Roche Products, Inc., has continuously since 1970 marketed in this country dosage form pharmaceutical products under the registered trademark Dalmane. These products contain flurazepam hydrochloride as the active ingredient and are prescribed for relief of insomnia.

Dalmane brand pharmaceutical products have enjoyed marked and widespread acceptance by the medical profession. Plaintiff indicates that its current sales of Dalmane brand products excede (sic) forty million dollars.

Because of the exclusive rights provided by a United States patent, Roche Products is the sole lawful manufacturer and user of this product, and the sole supplier of pharmaceutical products containing flurazepam hydrochloride in the United States.

Roche's patent will expire on January 17th, 1984, less than five months from now.

The defendant Bolar is engaged primarily in the manufacture and sale of generic pharmaceutical products that sometime duplicate successful brand name drugs developed, manufactured and sold in dosage form by so-called research-oriented or pharmaceutical companies.

The defendant Robert Schulman (sic) is the founder and President of Bolar.

Defendants Bolar and Schulman (sic) admit that they have obtained and presently possess five kilograms of the raw material which is the subject of the patent, and that they intend and plan to soon commence using it to make dosage form capsules, to perform stability tests, dissolution tests, and clinical bio-availability studies, and to use such cap-

sules, data and studies to seek approval from the Food and Drug Administration to commercially market dosage form capsules in competition with the Roche Products.

There is no dispute by defendant as to the validity of plaintiff's patent, and they assert that they have no intention of selling the product until the patent expires.

They seek, however, to be authorized to engage in sales the moment the patent expires.

There is little doubt that the action complained of, if committed in the first year of the patent, would constitute an infringement and would be enjoinable.

The defendants suggest, however, that the act should be viewed differently if they take place on the eve of the expiration of the patent and are preparatory to manufacture and sale once the patent expires when no infringement would or could exist.

The statute, however, makes no such exception. The monopoly granted is for the entire period. To hold otherwise would require a case by case determination of when such preparation could begin and what could be done in expectation of the expiration of the patent.

The Court sees little difference between testing and seeking approval in advance of the expiration date as opposed to other uses which would otherwise be considered infringement, even though no sale is contemplated.

In effect defendants argue that anything short of actual manufacture and sale should be permitted so as to allow for competition on the first day that the statute allows. Defendants contend that to do otherwise confers upon the patentee an extension of its monopoly, since competitors will be barred for a further extended period required to obtain the necessary approvals in order to commence production and sales.

That indeed may be the practical effect of the statute, but it does not warrant carving out an exception to the statute not granted by Congress. It would be a simple matter for Congress to declare that during the year prior to the expiration of a patent, others may use or make the patented item provided no sales take place until expiration.

The Congress, having failed to do so and having failed to provide any such exception, the Court should not do so.

No matter how minimal defendant's use of the patent may be, it should not be permitted to benefit from that illegal use even though it may not reap the benefits of such use until after the patent expires.

In addition to the presumption of irreparable harm which follows an infringement, the harm in this matter suffered by plaintiff is irreparable since defendant will, if permitted to continue, gain an advantage in the marketplace which they could not obtain but for the infringement.

The Court is concerned and recognizes that the injury will not actually occur until the patent has expired and competition is permitted, but the advantage gained by defendents has been gained by illegal means; therefore, the injury is occurring presently, although the effects may not be felt until after the patent expires and the monopoly ends.

The case is no different from a competitor manufacturing and stockpiling a patented item, but not selling it before the patent expires. Certainly there is irreparable injury even though it may not manifest itself until the future.

Additionally, the Court notes that monetary damages would be impossible to ascertain.

Therefore, the Court is satisfied that plaintiff has established a likelihood of success on the merits, and furthermore, that irreparable harm will occur if injunctive relief is not granted.

Furthermore, there is a great public interest in the protection of patented products. Assuming that when the patent expires the defendants may offer a comparable product at a reduced price, the advantage to the public at that time does not counterbalance the greater public interest in encouraging the research and development which patent protection fosters and encourages.

The Court would like to add one final note to this brief opinion.

As was stated prior to the argument, this case is assigned to Judge Debevoise and was heard by me on an emergency basis. I have ruled only that a Temporary Restraining Order should issue and, of course, I will provide for the issuance of the Order to Show Cause why a preliminary injunction should not be granted; however, in fairness and in deference to Judge Debevoise, my opinion in this matter should not be deemed to be the law of the case and Judge Debevoise should feel free to take a contrary position as to the law if he deems it appropriate, just as he would have had the right to do in considering a motion for preliminary injunction if he had decided the Temporary Restraining Order application in the first instance.

For those reasons the Court will grant the Temporary Restraining Order. It will be made returnable before Judge Debevoise on September 9th at 9 A.M., pursuant to the request of his Chambers.

There is a provision in the form of order for a bond. I don't know whether defendants require it. We are certainly dealing with a substantial company here.

What is your position on that?

MR. MARROW: A minimal bond would be sufficient.

THE COURT: What do you suggest?

MR. MARROW: A thousand dollars.

MR. DEL DEO: When will you need the thousand dollars?

THE COURT: I suppose we have to give you until Tuesday to file it.

MR. DEL DEO: File the bond?

THE COURT: Yes.

MR. DEL DEO: I can post my own check for a thousand dollars if you wish.

THE COURT: Why don't you do that. I think it is simpler than arranging for the bond. Why don't you post one thousand dollars security?

Is that satisfactory to counsel?

MR. MARROW: Yes.

THE COURT: What about service? Can we consider service being effected through counsel?

MR. MARROW: Yes, your Honor.

Are you referring to service of the moving papers?

THE COURT: And this Order to Show Cause, you will accept service?

MR. MARROW: We acknowledge receiving it.

THE COURT: All right.

MR. DEL DEO: Your Honor—

THE COURT: Recognizing that this will be heard on Friday, when will defendants be able to file answering papers with Judge Debevoise?

MR. MARROW: Monday is a holiday. I think we would need a few days next week.

THE COURT: Could you do it by, let's say, two o'clock on Wednesday, the 7th, we want him to have some time to read them.

If you have any problem you can call him, but I will insert that into the order.

Mr. Del Deo, do you wish to be heard?

MR. DEL DEO: Yes. What I would propose to do is give my personal check for a thousand dollars to the clerk, make it payable to the Clerk of the Court.

THE COURT: Yes.

MR. DEL DEO: And if it is all right with your Honor and with Mr. Marrow, I represent that the check is good and I will not stop a payment, but it would, I would just as soon if the clerk didn't cash it, but just hold it until Tuesday when I will replace it with a bond.

THE COURT: Or a check of your client. It may be more difficult—

MR. DEL DEO: I have my own check in my pocket. I can just make it out for a thousand dollars.

THE COURT: Is this really necessary? Should we bother at all with the thousand dollars?

MR. MARROW: I will waive it, Judge.

THE COURT: Thank you.

Anything else?

I have provided that it shall be returnable, as I have already indicated, before Judge Debevois (sic) at nine A.M. on September 9.

The defendant shall file any answering papers by two o'clock on the 7th, which is Wednesday.

If there are any reply papers, which I would discourage because it won't give Judge Debevoise much time to read them, but I have provided that they be filed by September 8th, two o'clock.

I will give it to the clerk. Thank you, gentlemen.

MR. DEL DEO: We will bring the order in. We have a form of order and we will fill it out.

THE COURT: I have just done it. If you want to review it, I have just done it and signed it. Even though it was entitled "Motion," to me it is an order.

Why don't you and counsel review it? If you see any problems with it let me know. I will be here for a while. I have just signed it and filled it out.

Order of United States District Court for the District of New Jersey

UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

Civil Action No. 83-2809 D

(Hon. Dickinson R. Debevoise)

CRUMMY, DEL DEO, DOLAN & PURCELL
A Professional Corporation
Gateway I
Newark, New Jersey 07102
(201) 622-2235
Attorneys for Plaintiff

ROCHE PRODUCTS INC.,

Plaintiff,

v.

BOLAR PHARMACEUTICAL CO., INC.,

Defendant.

Defendants, Bolar Pharmaceutical Co., Inc. and Robert Shulman (sic) having moved for an Order, through their attorneys, Siegel & Barz, and Salon, Marrow, Dyckman & Trager, dismissing the Complaint in this action pursuant to Rules 12(b)(3) and 12(b)(6) of the Federal Rules of Civil Procedure, and the Court having considered Defendants' Motion and Supporting Memorandum and Affidavit, and the

Memorandum in Opposition of Roche Products Inc., and the Court having heard and considered argument this day by counsel for the parties, and the Court being advised that so much of defendants' motion to dismiss under Rule 12 (b)(6) has been withdrawn,

It is on this 26th day of September, 1983

ORDERED that:

1. The caption of this action shall be Roche Products Inc. v. Bolar Pharmaceutical Co., Inc. by reason of the dismissal, without prejudice, of the action as to Robert Shulman (sic) by a Stipulation and Consent Order Pursuant to Rules 21 and 41(a) F.R.Civ.P. signed by counsel for the parties on September 16, 1983, and the entry on September 20, 1983 of a Consent Judgment as to SST Corp.;

2. Venue as to defendant Bolar Pharmaceutical Co., Inc. is improper in this judicial district;

3. To the extent that defendant's Motion seeks dismissal of the Complaint it is denied and the Court in the interest of justice directs that this action be transferred to the United States District Court for the Eastern District of New York which is a district in which this action could have been brought as to defendant Bolar Pharmaceutical Co., Inc. pursuant to 28 U.S.C. §1406(a);

4. The Clerk of this Court is directed to dispatch the papers in this action with all deliberate speed to the Clerk of the United States District Court for the Eastern District of New York and counsel for the parties are directed to

cooperate to the extent requested to do so by the Clerk of this Court to achieve speedy transmission and docketing of the action in the United States District Court for the Eastern District of New York.

5. The Temporary Restraining Order issued by the Honorable H. Lee Sarokin on September 2, 1983 which was continued in all respects to and including September 26, 1983 by a Stipulation and Consent Order of September 9, 1983 and which, pursuant to said Stipulation and Consent Order, could be extended to such other and different date as may be agreed to by counsel for the parties or as this Court shall otherwise direct, shall be and hereby is extended in all respects, pursuant to the consent of the parties heretofore given, to and including [Sept. 30, 1983 and thereafter if the parties consent thereto until—DRD] the date on which a Judge of the United States District Court for the Eastern District of New York hears the pending Motion of Roche Products Inc. for a Preliminary Injunction, which Motion has been briefed and was set for hearing before me on September 30, 1983.

Dated: Newark, New Jersey
September 26, 1983

So Ordered:

DICKINSON R. DEBEVOISE /s/

U.S.D.J.

Memorandum and Order of United States District Court for the Eastern District of New York

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

CV 83-4312

(Wexler, J.)

ROCHE PRODUCTS, INC.,

Plaintiff,

against

BOLAR PHARMACEUTICALS CO., INC.,

Defendant.

APPEARANCES:

JOHN C. VASSIL, P.C.
Morgan, Finnegan, Pine, Foley & Lee, Esqs.
Attorneys for Plaintiff
345 Park Avenue
New York, New York 10154

ROBERT V. MARROW, ESQ.
Salon, Marrow, Dyckman, & Trager, Esqs.
41 East 42nd Street
New York, New York 10017

WEXLER, J.

This matter comes before the court as an action to permanently enjoin certain acts as threatened infringement of

a patent. Suit was originally filed in U.S. District Court in New Jersey pursuant to 35 U.S.C. §§271 and 283, and under the grant of jurisdiction provided in 28 U.S.C. §1338. After District Judge H. Lee Sarokin issued a temporary restraining order on September 2, 1983, defendant was granted a change of venue pursuant to 28 U.S.C. §1406(a). District Judge Debevoise transferred venue to the Eastern District of New York for a hearing on the preliminary injunction, which was scheduled for October 5, 1983. At that time plaintiff moved to consolidate the hearing with a trial on the merits pursuant to Rule 65(a)(2) Fed.R.Civ. P. Defendant did not oppose and the court ordered the hearing consolidated with a trial on the merits.

Plaintiff Roche Products, Inc. (Roche) holds patent number 3,299,053 for flurazepam hydrochloride (flurazepam hcl). That compound is the active ingredient in a prescription sleeping pill manufactured by plaintiff under the brand name DALMANE. Plaintiff's seventeen year patent expires on January 17, 1984. Bolar Pharmaceutical Company (Bolar) is a generic drug company that duplicates drugs no longer under patent and sells the compounds to wholesale distributors. Bolar is in possession of five kilograms of flurazepam hcl, which it imported from a foreign manufacturer not subject to United States patent law. Plaintiff seeks to permanently enjoin defendant from performing required FDA experiments with the drug during the term of the patent.

There are no disputed facts in this case. There is no argument that the patent is for a pioneer invention and is valid and in force. Plaintiff's sales of DALMANE are in excess of $40,000,000 annually. There is no contention that Bolar will manufacture or sell flurazepam hcl before the

patent expires, nor is it contended that Roche has authorized Bolar to make, use or sell the drug. Defendant acknowledges that it is in possession of five kilograms of imported flurazepam hcl and freely admits that it intends to form the compound into capsules and commence the testing and experiments necessary for a New Drug Application to the Food and Drug Administration (FDA) before the January 17, 1984 expiration date of the patent.

Title 35 U.S.C. §271(a) provides in pertinent part:

> [W]hoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.

Plaintiff argues that putting the drug through the FDA required testing and experimentation before the patent expires constitutes infringement under section 271(a), even if there is no intent to make, sell or otherwise realize a monetary gain until after January 17, 1984. Roche asserts that such action constitutes a *use* prohibited by the law. Bolar concedes that its tests do not fall under the infringement exception known as experimentation for philosophical, amusement, or curiosity purposes. It maintains that its testing does not constitute infringement use because it is *de minimis,* it does not by its nature infringe and no commercial value or profit will be realized before the patent on the drug expires. The defendant characterizes its activity as limited pre-expiration preparation for post-expiration entry into the market.

The question before the court is a very narrow one: does the limited use of a patented drug for experiments strictly related to FDA drug approval requirements during the last six months of the term of the patent constitute use prohibited by 35 U.S.C. §271(a)? The court holds that it does not.

An underlying issue in this case is the procedure for getting FDA approval, without which a drug cannot be marketed. Bolar asserts that it will take two years to amass required data and obtain approval, in effect delaying entry into the market and extending the patent *de facto* for the same period. Roche claims that it is entitled to that delay in competition, but can point to no legal support. It can only be observed that patent protection is contained in a single, general body of law meant to apply to inventions of every sort, not only drug compounds. The delaying regulations of the FDA could hardly be considered a part of the monopoly benefits Congress sought to bestow. *See* 35 U.S.C. §154. Viewed from this vantage, what is at stake is a post-expiration competitive benefit for Bolar at Roche's expense.

The plaintiff urges the adoption of the reasoning and holding of the recent case of *Pfizer, Inc.* v. *International Rectifier Corp.*, 217 U.S.P.Q. 157 (C.D. Calif. 1982). There the district court in California had issued a 1980 injunction against defendant's activities as infringement of plaintiff's drug patent. Before that court were two years of post-injunction product testing and development involving at least 400 kilograms of the drug and apparently profitable overseas manufacture and sale. The defendant in *Pfizer* was clearly doing more, for a longer period of time than Bolar intends to do here. More significantly, in *Pfizer* the defendant was reaping commercial value in defiance of a court injunction. The substantial and long term acts in violation of an injunction present in *Pfizer* are not present in the case at bar. Consequently, this court declines to make a wholesale adoption of the California court's reasoning and holding.

The *Pfizer* court, although it draws on the analysis and reasoning of cases from all the circuits, is bound by the

Ninth Circuit Court of Appeals' reading of the law, which strictly limits the experimental use exception to purposes of amusement and philosophical gratification. *Spray Refrigeration Co.* v. *Sea Spray Fishing, Inc.*, 322 F.2d 34 (9th Cir. 1963). This court, of course, is not bound by the Ninth Circuit, and although plaintiff advocates their analysis, the court instead turns to the line of reasoning followed by the Court of Appeals for the Second Circuit.

Bolar's experimentation cannot be classified as merely for amusement or philosophical gratification. At the same time, it cannot be connected with any act of competition or profit during the term of the patent in either domestic or foreign markets. Its experimentation is commercial preparation of a nonproduction nature for post-expiration competition. In analagous cases this has been held a noninfringing use. In *Arko Agate* v. *Master Marble Co.*, 18 F. Supp. 305 (N.D.W.Va. 1937), the experimentation with a marble manufacturing device covered by plaintiff's patent prior to going into production was held not an infringing use. The use of the apparatus was clearly a commercial test, yet in the absence of any profit from the activity, the court found no infringement. Similarly, in *Dugan* v. *Lear Avia, Inc.*, 55 F. Supp. 223 (S.D.N.Y. 1944), *aff'd* 156 F.2d 29 (2d Cir. 1946), building and commercial testing of a device without commercial manufacture or sale was deemed not to be an infringing use. Again, in *Chesterfield* v. *United States*, 159 F. Supp. 371 (Ct. Cl. 1958), no infringement was found where the federal government conducted tests and experiments. Citing *Bosnack Mack Co.* v. *Underwood*, 73 F. 206 (C.C. 1896), the Court of Claims stated flatly, "Experimental use does not infringe." 159 F. Supp. at 375. Bolar's FDA-mandated testing clearly falls in line with the

sort of commercial experiments without profit, manufacture, or sale during the patent term that the Court of Appeals holds is non-infringing.

To find infringing use there must be a benefit at the expense of the patent. In *Kaz Manufacturing Co., Inc.* v. *Chesebrough-Pond's, Inc.*, 211 F. Supp. 815 (S.D.N.Y. 1962), *aff'd* 317 F.2d 679 (2d Cir. 1963), the court declared use to be "the commercially valuable use of which patentee could or would avail himself." The court held that as long as defendant was not helping himself to a benefit of a type secured by the patent, there was no infringement. Similarly, post-expiration advantage would not be a value secured by the patent. Furthermore, Bolar's activity cannot be connected with any benefit during the term of the patent.

In a like vein, the *de minimis* doctrine would seem to apply. Stated more fully, the law does not concern itself with small matters. In *Maxon Premix Burner Co.* v. *Eclipse Fuel Engineering Co.*, 471 F.2d 308 (7th Cir. 1972), the Seventh Circuit Court of Appeals held the experimental construction of a prototype even paired with a sale was *de minimis* and insufficient to support an action for threatened infringement. In the case at bar, Roche can point to no substantial loss that would stem from Bolar's studies. The only harm Roche can point to is a violation of the principle of its monopoly.

A court should be cautious in applying the equitable remedy of a permanent injunction in patent cases, *American Safety Device Co.* v. *Kurland Chemical Co.*, 68 F.2d 734 (2d Cir. 1934), particularly where, as here, there remains little more than three months to the term of the patent. This is doubly true where the case involves only a threatened infringement.

More importanly, the court cannot find a basis for holding that Bolar's limited experimental use of flurazepam hcl would constitute infringement. First, Bolar realizes no benefit during the term of the patent; its activities are in no way connected wilth current manufacture or sale here or abroad. Nor do its activities lessen Roche's profits during the patent's term. Second, post-expiration delay in competition unintentionally imposed by FDA regulation is not a right or benefit granted by the patent law. This court will not act to protect a right or benefit that is without legal basis. Third, Roche can point to no substantial harm it will suffer from Bolar's FDA studies before the patent expires. Bolar's threatened activity is at best *de minimis* and will not support an action for infringement.

If, however, it develops that Roche suffers substantial harm or loss during the patent's term, it still has available to it action at law for damages against Bolar.

Accordingly, no permanent injunction will issue and the temporary restraining order is dissolved. Parties will bear their own costs.

So Ordered.

/s/ Leonard D. Wexler

Leonard D. Wexler, U.S.D.J.

Dated: Brooklyn, New York
October 11, 1983

APPENDIX C

Judgment of United States District Court for the Eastern District of New York

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

CV 83 4312 (LDW)

ROCHE PRODUCTS, INC.,

Plaintiff,

against

BOLAR PHARMACEUTICALS CO., INC.,

Defendant.

A memorandum and order of Honorable Leonard D. Wexler, United States District Judge, having been filed on October 13, 1983, denying plaintiff's motion for a permanent injunction, dissolving the temporary restraining order, and dismissing the complaint without costs, it is

ORDERED and ADJUDGED that the plaintiff take nothing of the defendant; that plaintiff's motion for a permanent injunction is denied; that the temporary restraining order is dissolved; that the complaint is dismissed; and that the parties are to bear their own costs.

/s/ ROBERT C. HEINEMANN

Robert C. Heinemann
Clerk of Court

Dated: Brooklyn, New York
October 13, 1983

Judgment of United States Court of Appeals for the Federal Circuit

UNITED STATES COURT OF APPEALS

FOR THE FEDERAL CIRCUIT

No. 84-560, 83-4312 (LDW)

ROCHE PRODUCTS, INC.,

Appellant,

v.

BOLAR PHARMACEUTICAL CO., INC.,

Appellee.

ON APPEAL from the U. S. District Court for the Eastern District of New York

This CAUSE having been heard and considered, it is

ORDERED and ADJUDGED: REVERSED AND REMANDED, with instructions to fashion an appropriate remedy.

ENTERED BY ORDER OF THE COURT

George E. Hutchinson, Clerk

/s/ GEORGE E. HUTCHINSON
Clerk

DATED April 23, 1984

ISSUED AS A MANDATE:
May 15, 1984

APPENDIX D

U.S. Constitution

Section 8, Clause 8. Patents and copyrights

To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries;

Title 21 USC § 355

§ 355. New drugs—Necessity of effective approval of application

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.

Filing application; contents

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

Title 35 USC § 154

§ 154. Contents and term of patent

Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, for the term of seventeen years, of the right to exclude others from making, using, or selling the invention throughout the United States, referring to the specification for the particulars thereof. A copy of the specification and drawings shall be annexed to the patent and be a part thereof. July 19, 1952, c. 950, § 1, 66 Stat. 804.

Title 35 USC § 271

§ 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.

Title 35 USC § 283

§ 283. Injunction

The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable. July 19, 1952, c. 950, § 1, 66 Stat. 812.

APPENDIX E

Article in Volume 224 No. 4653 of *Science*, published by American Association for the Advancement of Science

Patents Encroaching on Research Freedom

A tradition of disregarding patent infringement when it involves experimental use of an invention may be eroding for biologists

Some two dozen researchers at universities, companies, and government laboratories recently received letters from Johnson & Johnson warning them that the use in research of particular cells that produce monoclonal antibodies may infringe the company's patent rights. The letter raises the tricky question of the extent to which patent law can be used to restrict research uses of patented products and processes.

A similar issue was raised recently in a court decision concerning clinical testing of a patented drug. The U.S. Court of Appeals for the Federal Circuit, which now hears all patent appeals, ruled that Bolar Pharmaceutical, a generic drug manufacturer, broke the law by testing its version of a drug made by Roche Products before Roche's patent had expired. Some patent attorneys are concerned that, if the ruling is interpreted broadly, it could be used to restrict a variety of research activities.

Although Johnson & Johnson's warnings and the contest between Roche and Bolar are not directly related, they both address an area of patent law that is in a considerable state of flux. The statutes spell out in plain language how a patent grants a 17-year monopoly to an inventor, prohibiting others from making, using, or selling the invention.

However, a tradition that began in the early 19th century has usually exempted experimental use of an invention from being construed as infringement. The issue at stake now is how to define when experimental use of patented technology becomes commercially threatening to an inventor and therefore no longer is entitled to that exemption. Some resolution of this ambiguity will be vital to the biotechnology industry, which is so heavily dependent on basic and near-basic research activities.

The contest between Roche and Bolar has been closely watched in the pharmaceutical industry. Early in 1983 Bolar began an effort to get federal approval to market flurazepam hydrochloride, the active ingredient in Roche's highly successful sleeping pill, whose trademark is Dalmane. Although the safety of this drug already was established, the Food and Drug Administration requires a generic drug manufacturer to prove it can meet the same standards. However, if the generic manufacturer is forced to wait until a drug's patent expires before such tests begin, the original manufacturer effectively gains a considerable extension on the patent's lifetime. [Legislation now being drafted by Representative Henry Waxman (D-Calif.) would resolve some of these problems (*Science*, 27 April, p. 369).]

Roche's patent for Dalmane expired on 17 January 1984, but Bolar began clinical trials long before that date. Roche brought a patent infringement suit against Bolar in July 1983. In October, the U.S. District Court in the Eastern District of New York ruled in Bolar's favor, but on 23 April 1984 that ruling was reversed on appeal. Bolar currently is planning to petition the Supreme Court to review the case, says attorney Robert Marrow, who represents the company.

"From the scientific point of view, the real threat [in the appeal court's decision] is it effectively prohibits any experiments with a patented product if it tends toward commercial development," Morrow says. "This is a far-reaching opinion that [could] negate the experimental use exception, unless it's for pure amusement."

Morrow's interpretation is something of a worst-case reading of the opinion handed down by Judge Philip Nichols, Jr. But other attorneys are also speculating about how far his opinion goes in this direction. "The experimental use exception is not gutted," says Jorge Goldstein, a patent attorney for a Washington, D.C. firm that represents a broad spectrum of corporate clients (but with no direct stake in the Roche-Bolar contest). "But for a company to argue that it's 'just doing research,' won't fly if it has a substantial commercial purpose."

The ruling "may not be a serious inroad" on the experimental exception to patents, says James Weseman, a patent attorney with a San Francisco law firm with biotechnology company clients. But certain passages in Judge Nichols' opinion where he uses "expansive language to define experimental use" are worrying, Weseman says.

For example, Nichols wrote: "Bolar's intended use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry [and] is thus an infringement. . . . We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes."

"The biotechnology industry is sensitive to anything that affects what they do best—research," Weseman con-

tinues. "If case law develops so that even in the earliest stages companies must avoid patent infringement, it will really restrict their abilities and stultify their research. There's plenty to worry about."

The recent actions by Johnson & Johnson could be another step toward restricting use of patents that is a cause for more worry. Johnson & Johnson patent attorney Geoffrey Dellenbaugh has been sending out letters to researchers warning against the use of particular monoclonal antibody-producing hybridomas, which the company has deposited with the American Type Culture Collection (ATCC) in the course of obtaining patents. "The fact that you have obtained samples of these hybridomas from the ATCC in no way grants you any right or license under our patents in the United States or other countries," one of the letters, sent to a researcher at the National Institutes of Health (NIH), says. "Your use of these hybridoma samples may constitute infringement of one or more of these patents, regardless of whether the thus-produced antibody is subsequently used or sold."

About two dozen researchers from universities, companies, and government research institutions including NIH are involved so far. The letters were sent out because of the concern that "people might use the cells in a way that infringes the patent and deprives us of sales of antibodies," explains Dellenbaugh. The cells can be obtained from ATCC at a nominal cost, whereas Johnson & Johnson's subsidiary, Ortho Diagnostics, is marketing the antibodies (for research and diagnostic purposes) to make a profit. The company quite naturally would like to protect its commercial interests and develop a market for its patented monoclonal antibodies. Researchers would like to use those

antibodies (some of them are to T cells, which are part of the immune system). And scientists with the right know-how undoubtedly can make the antibodies—from the company's cell lines, obtained perfectly legally from ATCC—more cheaply than they can be bought.

"The reason we wrote those letters was to inform people of the possible legal consequences. We intend, in appropriate circumstances, to protect our rights," Dellenbaugh says. The question, as with the Roche versus Bolar ruling, is "How far does that extend?" he adds. "If someone made an improvement that used your patented invention and uses that for commercial purposes—whether they're in a university or not—that is infringement of your patent."

"We've had correspondence with J&J, but have not resolved the issue," says NIH patent attorney Thomas Ferris. "We don't consider it infringement [for researchers to use cell lines] as long as it is experimental." In letters to Dellenbaugh, NIH patent attorneys have said, "[W]e will cooperate in your attempt to enforce your patent rights while at the same time recognizing that the interests of the research program of the [NIH] must be paramount, if it should prove to be more practicable to purchase hybridomas from ATCC for research purposes. We suggest that you promote your own sale of hybridomas by publicizing their availability to the NIH research community."

Dellenbaugh replied that each case should be considered individually, and that a determination should not rest "simply on whether the use is 'experimental.' . . . Since [there is] clear economic harm to Ortho, the rationale sometimes used for excepting experimental use from infringement should not apply."

NIH recently convened a meeting of its internal patent board, a group that includes patent attorneys and representatives from the various institutes, to consider the policy implications of the letters and has considered making recommendations on these issues to the Department of Health and Human Services. Currently, NIH is telling researchers "to go along the way they are."

Though Johnson & Johnson is not planning legal action to enforce its patent rights, according to Dellenbaugh, "If we decided an example needs to be made of an egregious infringement, we might do it." Hence, Ferris says, no matter what policy is laid down, such issues "ultimately can only be resolved in the courts."—JEFFREY L. FOX